

SPIRACUR INC.

SNaP® WOUND CARE SYSTEM  
SPECIAL 510(k) PREMARKET NOTIFICATION

**SECTION 6**  
**510(k) SUMMARY**

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510(k) Notification K112341

AUG 29 2011

**GENERAL INFORMATION**

**Applicant:**

Spiracur Inc.  
1180 Bordeaux Drive  
Sunnyvale, CA 94089  
U.S.A.  
Phone: 408-701-5300  
Fax: 408-701-5301

**Contact Person:**

Sarah L. Canio  
Experien Group, LLC  
755 N. Mathilda Avenue, Suite 100  
Sunnyvale, CA 94085  
U.S.A.  
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Email: sarah@experiengroup.com

**Date Prepared:** August 12, 2011

**Classification:**

21 CFR§878.4683, Class II

**Product Code:**

OKO

**Trade Name:**

SNaP® Wound Care System

**Generic/Common Name:**

Non-powered suction apparatus device intended for negative pressure wound therapy

**Predicate Device:**

SNaP® Wound Care System (K111393)

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**Intended Use:**

The SNaP Wound Care System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing through the removal of excess exudates, infectious material and tissue debris. The SNaP Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehiscent wounds, partial-thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions, flaps and grafts.

**Product Description:**

The SNaP Wound Care System is a non-powered, portable, single-use suction device intended for wound management via application of negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. The SNaP Wound Care System is designed to provide active wound treatment through the removal of excess exudates, infectious material and tissue debris. The SNaP Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehiscent wounds, partial-thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions, flaps and grafts. The SNaP Wound Care System utilizes dedicated constant-force springs to mechanically generate the negative pressure gradient.

The SNaP Wound Care System is used in conjunction with the SNaP Dressing Kit.

**Substantial Equivalence:**

This Special 510(k) premarket notification is for the SNaP Wound Care System, which is a modified version of the cleared SNaP Wound Care System (K111393). The minor design modification implemented to develop the modified SNaP System includes a change to the SNaP Dressing Kit to incorporate the use of a hydrophobic polyurethane foam. There have been no changes to the other components of the SNaP System as a result of this design change. The design modifications outlined in this Special 510(k) premarket notification do not (1) affect the intended use or (2) alter the fundamental scientific technology of the device. The modified SNaP System shares the same intended use, the same technological characteristics and the same principles of operation as the predicate device. The modified SNaP System and the cleared SNaP System (K111393) are both non-powered, portable, single-use suction devices intended for wound management via application of negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids and infectious materials. Both systems utilize dedicated constant-force springs to mechanically generate the negative pressure gradient. Any differences between the devices do not raise any new issues of safety or effectiveness.

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**Testing in Support of Substantial Equivalence Determination:**

The SNaP Wound Care System and its components were evaluated to ensure conformance to design specifications. The testing performed includes:

- Bench testing conducted on the modified SNaP Wound Care System to assess the ability to deliver negative pressure wound therapy comparable to the predicate device (K111393)
- Biocompatibility testing

**Summary:**

The SNaP Wound Care System is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Spiracur, Inc.  
% Experien Group, LLC  
Ms. Sarah Canio  
755 N. Mathilda Avenue  
Sunnyvale, California 94085

AUG 29 2011

Re: K112341  
Trade/Device Name: SNaP® Wound Care System  
Regulation Number: 21 CFR 878.4683  
Regulation Name: Non-Powered suction apparatus device intended for negative pressure wound therapy  
Regulatory Class: II  
Product Code: OKO  
Dated: August 12, 2011  
Received: August 15, 2011

Dear Ms. Canio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

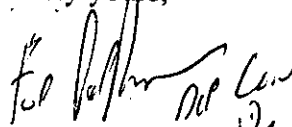
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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**SECTION 5**  
**INDICATIONS FOR USE STATEMENT**

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510(k) Number (if known): K112341

Device Name: SNaP® Wound Care System

**Indications For Use:**

The SNaP® Wound Care System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing through the removal of excess exudates, infectious material and tissue debris. The SNaP Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehiscent wounds, partial-thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions, flaps and grafts.

Prescription Use X  
(21 CFR Part 801 Subpart D)

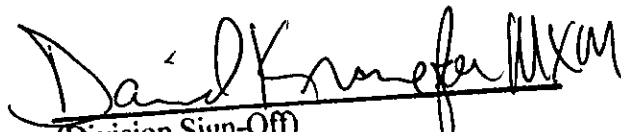
And/Or

Over the Counter Use \_\_\_\_\_  
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K112341